

DETAILED ACTION

Acknowledgements

Applicant's arguments, filed November 5, 2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1, 2, 6, 10, 11 and 23 – 39 are pending. Claims 6, 11, 26 and 29 – 39 are withdrawn as not being drawn to the elected invention. Claims 1, 2, 10, 23 – 25, 27 and 28 are currently under examination.

Comments and Notes

While claims 6 and 29 – 32 are not currently under examination, the labeling of the chemical formulae in these claims is improper. Each chemical structure must have its own formula number. In these claims, up to 9 different ring structures are identified by the same formula number.

Specification

1. The disclosure was objected to because of the inclusion of new matter. This rejection is MAINTAINED IN PART.

Figures 1 and 2 still contain tables in which a horizontal line appears to recite a set of substituents that are not supported in the original disclosure. The similar tables in figures 3 and 5 – 7 have been removed. However, without any indication as to where support for these ring structures can be found in the original specification, the objection to new matter in all of these figures is maintained.

The omission of the stereochemistry in one list of compounds as well and a second list of five- and six-membered ring compounds has been corrected.

2. The disclosure was objected to because of the inclusion of abbreviations were used that were not spelled out the first time they were used. This rejection is MAINTAINED.

Of the abbreviations mentioned in the Office Action mailed October 12, 2007, DADMAC has been removed, but the abbreviations PVM, MA and PABA remain in the specification and are not accompanied by the full name of the compound the first time the abbreviation is used.

3. The Examiner gratefully acknowledges the receipt of a substitute specification.

Claim Objections

4. Claims 1, 2, 10 and 25 were objected to because the chemical structure was not included in the claims but was in a figure. This has been corrected so the objection is WITHDRAWN.
5. Claims 2, 10, 27 and 28 were objected because of improper Markush group language. This has been corrected so the objection is WITHDRAWN.
6. Claims 23, 24, 27 and 28 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claim 1 has been amended to the closed language of "consisting of" from the open language of "comprising". The dependent claims 23, 24, 27 and 28 require the inclusion of additional ingredients that cannot be present due to the closed language of the independent claim from which these claims depend. For the purposes of applying art, these claims will be interpreted using open claim language that allows for the inclusion of other ingredients.

Claim Rejections - 35 USC § 112

7. Claim 10 was rejected because the same chemical species was repeated in the list. This has been corrected so this rejection is WITHDRAWN.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 1, 2, 10, 23 – 25, 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. If claim 1 is interpreted as a matrix metalloprotease inhibitor composition, there is no support in the specification as filed for a composition consisting only of 2,4-dihydroxyacetophenone. Examples 5, 6, and 10 contain 2,4-dihydroxyacetophenone in the presence of additional ingredients. None of the examples contain a combination of only 2,4-dihydroxyacetophenone and one carrier base as in one possible closed interpretation of claims 23 and 27 nor a combination of only 2,4-dihydroxyacetophenone and a divalent metal ion as in one possible closed interpretation of claims 24 and 28.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 1, 2, 10, 23 – 25, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “a matrix metalloprotease inhibitor” can be interpreted as a single molecular entity. How a single molecular entity can consist of multiple hydroxyaryl compounds is not understood and therefore this claim is vague and indefinite.

Claim Rejections - 35 USC § 102

12. Claim 1 was rejected over Möller et al. (WO 03/03045 A1). This rejection is maintained for the reasons of record set forth in the Office Actions mailed August 22, 2007 and October 12, 2007 as well as stated below.

Applicant has amended this claim from the open language of “comprising” to the closed language of “consisting of”. This means that the claim now reads on the hydroxyaryl compounds that contain an alkyl side chain with a ketone group. The disclosure of Möller et al. states (p 43 on the English translation) that the aldehyde or ketone of formula I was added. Prior to addition to the composition, the compound was present without any other ingredients. The existence of the compound in a state without other ingredients present is known and thus reads on claim 1 of the instant application. If the hydroxyaryl compound that contains an alkyl side chain with a ketone group by itself is able to inhibit matrix metalloproteases, this ability is inherent to the compound.

MPEP 2112 states that "the discovery of a previously unappreciated property ... does not render the old composition patentably new to the discoverer."

Claim Rejections - 35 USC § 103

13. Claims 1, 2, 10, 23 – 25, 27 and 28 were rejected over Möller et al. (WO 03/03045 A1). This rejection is maintained for the reasons of record set forth in the Office Actions mailed August 22, 2007 and October 12, 2007 as well as stated below.

As discussed above, the particular aldehyde or ketone compound exists in a state without other ingredients prior to addition to the composition. 2,4-dihydroxyacetophenone is one such compound aldehyde or ketone compound. If 2,4-dihydroxyacetophenone by itself is able to inhibit matrix metalloproteases, this ability is inherent to the compound. MPEP 2112 states that "the discovery of a previously unappreciated property ... does not render the old composition patentably new to the discoverer."

Double Patenting

14. Claims 1, 2, 10, 23, 25 and 27 were provisionally rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1, 5, 13 and 18 of copending Application No. 10/908,816. Those claims in the copending Application have

been cancelled so the provisional obviousness-type double patenting rejection is WITHDRAWN.

Response to Arguments

Applicant argues that the change to closed language means that the compositions of Möller et al. no longer apply to the claims as they require the presence of two small molecular organic ingredients. While this change in claim language means that the compositions taught by Möller et al. no longer read on the claims of the instant application. The amended claims of the instant application now read on 2,4-dihydroxyacetophenone by itself. This compound was used in the preparation of the compositions of Möller et al. and therefore the claims of the instant application are either anticipated by or made obvious by teachings of Möller et al. as discussed above. The dependent claims that require the presence of additional ingredients, conflicting with the closed language of the independent claim, have been interpreted using open language and thus the compositions of Möller et al. still applies to these claims.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 5 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718 or Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NMW

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 4173